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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,459	05/31/2000	MERVYN JOSEPH FREDERICK	0/97322US	8345

6449 7590 05/16/2005

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,459

Applicant(s)

FREDERICK ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt of Amendment and remarks received on January 14, 2005 is acknowledged. Claims **1-10** are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites, "A method for the aseptic packaging of a medicated intravaginal ring comprising placing the ring into a sachet consisting of a polyethylene-aluminum foil laminate and a polyester outer layer and further consisting of a plastic rib-and-groove reclosing means..." is vague and indefinite. The claim recites closed claimed language and thus the sachet cannot "further consist of". The examiner suggests restructuring the claim. One suggestion is "a sachet consisting of a polyethylene-aluminum foil laminate, a polyester outer layer, and a plastic rib-and-groove reclosing means..."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,544,546 to Groenewegen et al in view of FR 2748994.

Groenewegen et al teach a ring shaped device containing a medicament. See abstract. The device is preferably a vaginal ring used for hormonal replacement therapy or contraception. See column 2, lines 10-13. The reference teaches sterilizing the ring and packing it in a usual manner such as a placing the ring in a sachet consisting of a PET (12 microns), aluminum (9 microns), and LDP (Low Density Polyethylene 40 microns) laminate.

Groenewegen does not specify if the package is resealable.

FR teaches a package for contraceptive wherein the packaging can be resealed with a flap on the pocket part of the package. The resealable package allows for convenient disposal of the used contraceptive. See abstract.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Groenewegen and FR and utilize a reclosable package. One would have been motivated to do so since FR teaches a reclosable package allows for convenient and hygienic disposal of contraceptive devices. Therefore, one would have been

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motivated to add the reclosable flap to Groenewegen's package to provide for hygienic disposal of the contraceptive ring.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,544,546 to Groenewegen et al in view of JP 7-223653.

Groenewegen et al teach a ring shaped device containing a medicament. See abstract. The device is preferably a vaginal ring used for hormonal replacement therapy or contraception. See column 2, lines 10-13. The reference teaches sterilizing the ring and packing it in a usual manner such as a placing the ring in a sachet consisting of a PET (12 microns), aluminum (9 microns), and LDP (Low Density Polyethylene 40 microns) laminate.

Groenewegen does not teach a rib groove reclosing means.

JP teaches a laminated packaging bag comprising a seal that surrounds the bag and a sliding clasp fastener. The bag comprises laminated layers of paper/polyethylene/aluminum/polyethylene and cellophane(15-50 microns)/paper(50-100 microns/polyethylene (10-30 microns)/aluminum (7-10 microns)/polyethylene (20-50 microns). The packaging material is utilized for various products including, medical products, and chemical material. See page 4 of translated document. The package provides air tightness and stability to the package contents. See page 5. Further, the package prevents the package from leaking. See page 6. On page 11, a polyester layer is taught.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Groenewegen and JP and utilize JP's laminated bag for Igarashi's vaginal ring. One would have been motivated to do so since JP teaches a package that provides stability and air tightness for the contents contained within. Further, JP's bag prevents

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leakage of the package contents. Therefore, a skilled artisan would have been motivated to utilize JP's closure to ensure the sterility of Groenewegen's medicated ring and prevent leakage of the medication.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,544,546 to Groenewegen et al in view of JP 7-223653.

Groenewegen et al teach a ring shaped device containing a medicament. See abstract. The device is preferably a vaginal ring used for hormonal replacement therapy or contraception. See column 2, lines 10-13. The reference teaches sterilizing the ring and packing it in a usual manner such as a placing the ring in a sachet consisting of a PET (12 microns), aluminum (9 microns), and LDP (Low Density Polyethylene 40 microns) laminate.

Groenewegen does not teach a rib groove reclosing means.

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It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Groenewegen and JP and utilize JP's laminated bag for Igarashi's vaginal ring. One would have been motivated to do so since JP teaches a package that

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provides stability and air tightness for the contents contained within. Further, JP's bag prevents leakage of the package contents. Therefore, a skilled artisan would have been motivated to utilize JP's closure to ensure the sterility of Groenewegen's medicated ring and prevent leakage of the medication.

Conclusion

None of the claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG


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SUPERVISORY PATENT EXAMINER
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